

SUPPORTING STATEMENT - OMB NO. 0579-0015
RESTRICTED AND CONTROLLED IMPORTATION OF ANIMAL AND POULTRY
PRODUCTS AND BYPRODUCTS INTO THE UNITED STATES

June 2012

INTRODUCTION - Several commodities in the previously approved information collection have been separated out into three additional new collections (1) Prohibited and Restricted Importation of Fresh (frozen or chilled) pork or pork products into the United States, (2) Prohibited and Restricted Importation of Animal and Poultry Products (*Milk, Eggs*) into the United States, and (3) Prohibited and Restricted importation of Hams into the United States for streamlining purposes. Animal and Plant Health Inspection Service (APHIS) feels that it can more accurately account for information being collected with the separation of collection 0015 into 4 collections. These four collections will present a more accurate account of the information being collected.

A. Justification

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

The Animal Health Protection Act (AHPA) of 2002 is the primary Federal law governing the protection of animal health. The law gives the Secretary of Agriculture broad authority to detect, control, or eradicate pests or diseases of livestock or poultry. The Secretary may also prohibit or restrict import or export of any animal or related material if necessary to prevent the spread of any livestock or poultry pest or disease.

The AHPA is contained in Title X, Subtitle E, Sections 10401-18 of P.L. 107-171, May 13, 2002, the Farm Security and Rural Investment Act of 2002.

Disease prevention is the most effective method for maintaining a healthy animal population and for enhancing APHIS ability to compete globally in animal and animal product trade.

In connection with this mission, APHIS enforces regulations regarding both the importation of controlled materials and the prevention of foreign animal disease incursions into the United States. These regulations can be found at title 9, chapter I, subchapter D, parts 94, 95, 96 and 122 of the *Code of Federal Regulations* (CFR).

APHIS engages in a number of information collection activities to prevent or control the spread of livestock diseases via the importation of restricted and controlled animal products into the United States.

APHIS is asking OMB to approve its use of these information collection activities for an additional 3 years.

2. Indicate how, by whom, how frequently, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

APHIS uses the following information activities to enforce regulations regarding both the importation of controlled materials and the prevention of foreign animal disease incursions into the United States.

Certificate from Inspector Stating Conveyance Has Been Cleaned

During pre-clearance at foreign ports of exit, garbage on or removed from a vehicle is considered regulated garbage if the vehicle has been in any port outside the United States and Canada within the previous 2 years. However, garbage on or removed from a vehicle (other than an aircraft) is exempt from APHIS restrictions if the vehicle is accompanied by a certificate from an inspector of the Foreign Federal government stating that the vehicle was cleared of all garbage, cleaned, and disinfected in the presence of said inspector. This is performed to provide USDA assurances that there will be no introduction of exotic animal and plant pests. The certificate must physically accompany the shipment.

Application for Approval or Report of Inspection of Establishment Handling Restricted Animal Byproducts or Controlled Materials (VS 16-25)

Restricted animal products, byproducts, and controlled materials, including carcasses or parts or products of carcasses of poultry, game birds, and other birds, (for both nonprofit and business uses) may be imported for consignment to any museum, educational institution, or other establishment if, among other requirements, the establishment is inspected and approved by USDA using the VS Form 16-25. The VS 16-25 serves as an inspection report to help ensure that USDA-approved establishments are handling restricted and controlled imports in compliance with APHIS regulations. The VS 16-25 is completed by a U.S. Federal animal health official who acquires this information from U.S. establishment operators.

Agreement for Handling Restricted Imports of Animal Byproducts and Controlled Materials (VS 16-26)

Restricted animal products, byproducts, and controlled materials, including carcasses or parts or products of carcasses of poultry, game birds, and other birds, may be imported for consignment to any not-for-profit museum, educational institution, or other establishment if, among other requirements, the establishment signs the VS 16-26. The VS 16-26 provides APHIS with evidence that the establishment has the equipment, facilities, and capabilities to store, handle, process, or disinfect such articles to prevent the introduction or dissemination of Exotic Newcastle Disease (END), Foot-and-Mouth Disease (FMD), and rinderpest into the United States. The form also shows that APHIS has approved the establishment as evidenced by completion and endorsement of the form by APHIS officials. The operator of the establishment is required to sign this form.

Application for Permit to Import or Transport Controlled Material or Organisms or Vectors (VS 16-3)

Carcasses or parts or products of carcasses of poultry, game birds, and other birds from regions where END is considered to exist, and that do not otherwise qualify for importation, may be imported (for nonprofit and business uses) only if the importer, using the VS 16-3, applies for and is granted a permit by APHIS authorizing such importation. This information enables APHIS to carefully scrutinize the products and determine what, if any, disease threat they may pose to the U.S. poultry population. If APHIS decides to issue an import permit, information on the VS 16-3 also enables

APHIS to determine the appropriate safeguard measures. APHIS can then provide port and border personnel with appropriate clearance instructions for the impending shipment.

Application for Permit to Import or Transport Controlled Material or Organisms or Vectors (VS 16-3)

Eggs, other than hatching eggs, from regions where END is considered to exist, may be imported into the United States if they are to be used for scientific, educational, or research purposes; or if they have been cooked or processed; and, if APHIS has determined that the eggs can be imported under conditions that will prevent the introduction of END into the United States. Not for profit importers must obtain an APHIS-issued import permit before importation by completing the permit application and submitting it to APHIS in writing or electronically. The eggs must be moved and handled as specified on the permit.

Place Placards on Vehicles and Statement on Manifest, Bills of Lading, or Waybills

Transportation companies or operators of cars, trucks, or other vehicles carrying import products or materials moving under restriction, other than those in tight cases or casks, must affix to and maintain on both sides of all such vehicles, durable placards not less than 5 ½ by 6 inches in size, on which must be printed with permanent black ink and in boldface letters not less than ½ inch in height, the words: “Restricted Import Product Clean and Disinfect this Car or Truck.” Each of the waybills, conductors’ manifests, memoranda, and bills of lading pertaining to such shipments must have the words: “Restricted import product, clean and disinfect car or truck,” plainly written or stamped upon its face.

Certification from a National Government for Gelatin from Non-BSE Countries or from Non-bovine Species

Gelatin derived from horses or swine, or from ruminants that have not been in any bovine spongiform encephalopathy (BSE)-affected region, must, at the time of entry into the United States, be accompanied by an official certificate issued by the government of the region of origin. The certificate must state the species of animal the gelatin is derived from, or if the gelatin is derived from ruminants, certify that those ruminants have not been in any BSE-affected region. This certification provides APHIS with assurances that imported gelatin is not a BSE risk to the United States. The certificate must physically accompany the shipment.

Certificate Issued by a National Government for Importation of Hides and Skins

Governments of the regions of origin must complete a certificate bearing the seal of the proper department. The certificate ensures that abattoir hides or skins taken from animals slaughtered under government supervision were taken from animals slaughtered in the specified abattoir and found free from anthrax, FMD, and rinderpest. The certificate must physically accompany the shipment.

Certificate from a National Government for Import of Wool, Hair, Bristles

Governments of the regions of origin must complete a certificate bearing the seal of the proper department. The certificate ensures that the described wool, hair, or bristles were taken from animals slaughtered in the specified abattoir and found free from anthrax, FMD, and rinderpest. The certificate must physically accompany the shipment.

Certificate from a National Government for Import of Glue Stock

Glue stock originating in and shipped directly from a region recognized by APHIS as free of FMD or rinderpest may be imported into the United States without other restrictions, if, in addition to compliance with other APHIS regulations, the government of the region of origin provides a certificate

bearing the seal of the proper department and signed by an official veterinary inspector. The certificate must show that the glue stock was taken from animals slaughtered in the specified abattoir and found free from anthrax, FMD, and rinderpest. The certificate must physically accompany the shipment.

Application for Permit to Import or Transport Controlled Material or Organisms or Vectors (VS 16-3)

Importers, both nonprofits and businesses, must submit a written VS import permit application to APHIS to receive stomachs or portions of the stomachs of ruminants or swine, other than those imported for food purposes under USDA meat-inspection regulations. The import permit application asks for the exporter, a description of the permitted material, the proposed use of the imported material, final disposition of the permitted material, and any treatments to the imported material that may inactivate diseases of APHIS, VS concern. Permitted imports will be subject to any restrictions that APHIS deems necessary.

Application for Permit to Import or Transport Controlled Material or Organisms or Vectors (VS 16-3)

Importers, both nonprofits and businesses, must submit a written VS import permit application to APHIS to receive manure of horses, cattle, sheep, other ruminants, and swine. The import permit application asks for the exporter, a description of the permitted material, the proposed use of the imported material, final disposition of the permitted material, and any treatments to the imported material that may inactivate diseases of APHIS, VS concern. Permitted imports will be subject to any restrictions that APHIS deems necessary. Manure produced by animals transiting to the United States will be subject only to the USDA regulations governing the import of domestic livestock and other animals.

Report of Telegraph of Emergency Unloading of Restricted Import Products

If it is necessary to unload, en route, any restricted material or products transported in a placarded car, truck, or other vehicle, the carrier must then clean and disinfect the vehicle and any part of a premises that may have had contact with the material or product during unloading or reloading. The carrier must report the unloading incident by telegraph to the Deputy Administrator for Veterinary Services. This report must include such information as the nature of the emergency, the place where the material was unloaded, the original points of shipment and destination, the number and materials of the original vehicle, and the number and initials of the vehicle into which the material was reloaded in case the original vehicle was not used.

Certificate from a National Government for Importation of Foreign Animal Casings

No animal casings can be imported into the United States from any foreign region unless they are accompanied by a certificate completed and signed by the Government of the region where the animals were slaughtered and the casings collected, or by a non-government veterinarian authorized by the national government stating that the casings meet the criteria described in the Foreign Official Certificate for Animal Casings. A certificate issued by a non-government veterinarian is valid only if the certificate is endorsed by a veterinarian salaried by the national government of the region in which the animals were slaughtered and the casings were collected. This document certifies that the animals from which casings were derived were healthy and underwent veterinary inspection. It also certifies that the casings were clean, sound, and handled in a sanitary manner. The certificate must physically accompany the shipment.

Compliance Agreement (PPQ Form 519)

Any business engaged in handling or disposing of regulated garbage must first enter into a compliance agreement stating that the person agrees to comply with all APHIS regulations regarding this activity. The compliance agreement helps APHIS ensure that regulated garbage is handled and disposed of in such a way as to prevent the dissemination of livestock or poultry diseases into or within the United States. Although APHIS requires the compliance agreement to be completed, the Agency does not complete, review, or receive these documents; Customs Border Patrol receives them.

Application for Permit to Import or Transport Controlled Material or Organisms or Vectors (VS 16-3)

U.S. importers, both nonprofits and businesses, must submit an application in writing to APHIS for permission to import organisms or vectors into the United States, or transported from one State, Territory, or the District of Columbia to another State, Territory, or the District of Columbia. The application contains the importer's name, address, telephone number, fax number, a description of the products to be imported, the quantity and frequency of importation, the proposed use of the material, a description of the applicant's facilities for handling the material, the qualifications of the technical personnel who will be working with the material, and a description of any processing the material may have undergone before entering the United States. This information enables APHIS to scrutinize the products and determine what, if any, disease threat they may pose to the U.S. livestock population. If APHIS decides to issue an import permit, information on the VS 16-3 enables officials to determine the appropriate safeguarding measures for the importation. APHIS can then provide port and border personnel with appropriate clearance instructions.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

The VS Form 16-3 can be submitted through USDA's e-permitting system. It can be found on the Internet at <https://epermits.aphis.usda.gov/epermits>

Currently, the VS Form 16-25 and VS Form 16-26 are not available through the Internet; however, they have been incorporated into the Veterinary Services Process Streamlining (VSPS) initiative currently under development. Within VSPS will be the capability to complete the VS Form 16-25 and 16-26 electronically.

Depending on local PPQ and DHS accessibility to SharePoint, the Compliance Agreement may be available electronically. If there is no access to SharePoint, then the Compliance Agreement cannot be completed electronically.

Certificate from Inspector Stating Conveyance is Clean must physically accompany the conveyance; therefore, it is not a candidate for electronic submission.

The Certification of a National Government for Gelatin from Non-BSE Countries or from Non-Bovine Species must physically accompany the shipment; therefore, it is not a candidate for electronic submission.

The Certificate of a National Government for Importation of Hides and Skins must physically accompany the shipment; therefore, it is not a candidate for electronic submission.

The Certificate of a National Government for Import of Wool, Hair, or Bristles must physically accompany the shipment; therefore, it is not a candidate for electronic submission.

The Certificate of a National Government for Import of Glue Stock must physically accompany the shipment; therefore, it is not a candidate for electronic submission.

The Report of Telegraph of Emergency Unloading of Restricted Import Products cannot be recorded electronically because the carrier must report the unloading incident by telegraph to APHIS. Therefore, it is not a candidate for electronic submission.

The Certificate of a National Government for Importation of Foreign Animal Casings must physically accompany the shipment; therefore, it is not a candidate for electronic submission.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purpose described in item 2 above.

The information that APHIS collects in connection with this effort is not available from any other source. APHIS is the only Federal Agency responsible for preventing communicable diseases of livestock or poultry from entering the United States.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

The information APHIS collects is the absolute minimum needed to protect the United States from the introduction of animal diseases by importing foreign animal and poultry byproducts, organisms, and vectors.

APHIS has no small entities involved with this information collection.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

If this information were collected less frequently or not collected, the United States would be at increased risk for the introduction of rinderpest, FMD, ASF, CSF, or SVD. This would cause serious economic consequences to several U.S. livestock industries and potentially serious health consequences for U.S. livestock.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with the general information collection guidelines in 5 CFR 1320.5.

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;**
- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
- **requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

The information collection is conducted in a manner consistent with the guidelines established in 5 CFR 1320.5.

8. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting form, and on the data elements to be recorded, disclosed, or reported. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, soliciting comments on the information collection prior to submission to OMB.

In 2011, APHIS engaged in productive consultations with the following individuals concerning the information collection activities associated with this program:

Ellen Paul
 The Ornithological Council
 5107 Sentinel Drive
 Bethesda, MD 20816
 Telephone (301) 986-8568
 ellen.paul@verizon.net

Philip Mizrahie
 Pet Center
 4105 W. Jefferson Blvd
 Los Angeles, California 90016

Telephone 323-734-1445
Debbie@petcenter.com

Sharon Jones-Rogers
SAFC Biosciences
13804 West 107th Street
Lenexa, Kansas, 66215
Telephone (913) 253-3622
sharon.jones-rogers@sial.com

On Monday, February 27, 2012, pages 11482 - 11483, APHIS published in the Federal Register, a 60-day notice seeking public comments on its plans to request a 3-year renewal of this collection of information. During that time, APHIS received one comment from a concerned citizen about her perception of the general maltreatment of animals and the general disregard of the environment by USDA-APHIS. It had no relevance to the purpose of the collection.

9. Explain any decision to provide any payment or gift to respondents, other than reenumeration of contractors or grantees.

This information collection activity involves no payments or gifts to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

No additional assurance of confidentiality is provided with this information collection. Any and all information obtained in this collection shall not be disclosed except in accordance with 5 U.S.C. 552a.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior or attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

This information collection activity will ask no questions of a personal or sensitive nature.

12. Provide estimates of the hour burden of the collection of information. Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated.

• Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. If this request for approval covers more than one

form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.

See APHIS Form 71. Burden estimates were developed by increasing 2007 figures by 15% to adjust for inflation.

1. Mexican government officials estimate that the average hourly wage for foreign government officials, animal health officials, and inspectors to be **\$12.39**
2. The estimated hourly wage of full-time salaried veterinarian employed by the region of export is **\$21.63**. This figure was arrived at by the average of the following contacts: The Canadian Food Inspection Agency (\$50.31); the APHIS contact in the South Africa (\$3.81); and the Mexican government (\$10.78).
3. Industry contacts provided the hourly wage of managers of foreign facilities that process restricted animal materials to be **\$53.89**.
4. The Department of Labor's (DOL) Web site indicates the average hourly wage of importers (adjusted for inflation 15%) to be **\$8.68**.
5. The Laborsta International Web site indicates the average hourly wage for exporters for agriculture, meat, and foods, adjusted for inflation to be **\$10.29**.
6. The DOL Web site indicates the average hourly wage (adjusted for inflation 15%) of individuals transiting various commodities not eligible for importation into the United States to be **\$8.69**.
7. The DOL Web site indicates the average hourly wage of transportation companies, carriers, or operators of cars, trucks, or other vehicles (adjusted for inflation 15%) to be **\$15.27**.

• Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories.

APHIS estimates the total annual cost to these respondents to be \$61,317.30. APHIS arrived at this figure by multiplying the hours of estimated total burden (3,279 hours) by the estimated average hourly wage of the above respondents (\$18.70). The hourly rates for respondents of foreign countries were derived from the following source: Laborsta Internet Web site and consultations with foreign industry contacts. The hourly rates for U.S. respondents were derived from the is the hourly rate derived from the U.S. Department of Labor, Bureau of Labor Statistics May 2011 Report - Occupational Employment and Wages in the United States. See <http://www.bls.gov/news.release/pdf/ocwage.pdf>.

13. Provide estimates of the total annual cost burden to respondents or recordkeepers resulting from the collection of information (do not include the cost of any hour burden shown in items 12 and 14). The cost estimates should be split into two components: (a) a total capital and start-up cost component annualized over its expected useful life; and (b) a total operation and maintenance and purchase of services component.

No annual cost burden is associated with capital and startup costs, operation and maintenance expenditures, and purchase of services.

14. Provide estimates of annualized cost to the Federal government. Provide a description of the method used to estimate cost and any other expense that would not have been incurred without this collection of information.

The annualized cost to the Federal government is estimated at **\$112,669.19**. (See APHIS Form 79).

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-1.

Several commodities in the previously approved information collection have been separated out into three additional new collections (1) Prohibited and Restricted Importation of Fresh (frozen or chilled) pork or pork products into the United States, (2) Prohibited and Restricted Importation of Animal and Poultry Products (*Milk, Eggs*) into the United States, and (3) Prohibited and Restricted importation of Hams into the United States) for streamlining purposes. APHIS feels that it can more accurately account for information being collected with the separation of collection 0015 into 4 collections. These four collections will present a more accurate account of the information being collected.

ICR Summary of Burden:						
N	Requested	Program Change Due to New Statute	Program Change Due to Agency Discretion	Change Due to Adjustment in Agency Estimate	Change Due to Potential Violation of the PRA	Previously Approved
Annual Number of Responses	4,477	0	0	-17,776	0	22,253
Annual Time Burden (Hr)	3,279	0	0	-19,825	0	23,104
Annual Cost Burden (\$)	0	0	0	0	0	0

With the separation of the previously approved collection, there is an adjustment decrease of -7052 respondents and -17,776 responses resulting in a decrease of -19,825 total burden hours.

16. For collections of information whose results are planned to be published, outline plans for tabulation and publication.

APHIS has no plans to publish information it collects in connection with this program.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

Form VS 16-3 is used in a number of information collections; therefore, it is not practical to include an OMB expiration date because of the various collection expiration dates. APHIS is seeking approval to not display the OMB expiration date on this form.

18. Explain each exception to the certification statement identified in the "Certification for Paperwork Reduction Act."

APHIS can certify compliance with all provisions under the Act.

B. Collections of Information Employing Statistical Methods

There are no statistical methods associated with the information collection activities used in this program.